



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3322-FN]

Medicare and Medicaid Programs: Continued Approval of the American Association for Accreditation of Ambulatory Surgery Facilities Rural Health Clinic Accreditation Program.

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Final notice.

SUMMARY: This final notice announces our decision to approve the American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF) for continued recognition as a national accrediting organization for Rural Health Clinics (RHCs) that wish to participate in the Medicare or Medicaid programs.

DATES: This final notice is effective March 23, 2016 through March 23, 2022.

FOR FURTHER INFORMATION CONTACT:

Monda Shaver, (410) 786-3410, or Patricia Chmielewski, (410) 786-6899.

SUPPLEMENTARY INFORMATION:

I. Background

A healthcare provider may enter into an agreement with Medicare to participate in the program as a Rural Health Clinic (RHC) provided certain requirements are met. Sections 1861(aa)(1) and 1905(l)(1) of the Social Security Act (the Act), establish distinct criteria for facilities seeking designation as a RHC. Regulations concerning Medicare provider agreements are at 42 CFR part 489 and those pertaining to the survey and certification for Medicare participation of providers and certain types of suppliers are at 42 CFR part 488. The regulations

at 42 CFR part 491, subpart A specify the conditions that a provider must meet to participate in the Medicare program as a RHC.

Generally, to enter into a Medicare provider agreement, a facility must first be certified by a state survey agency as complying with the conditions or requirements set forth in part 491, subpart A, of our Medicare regulations. Thereafter, the RHC is subject to periodic surveys by a state survey agency to determine whether it continues to meet these conditions. However; there is an alternative to certification surveys by state agencies. Accreditation by a nationally recognized Medicare accreditation program approved by the Centers for Medicare & Medicaid Services (CMS) may substitute for both initial and ongoing state review.

Section 1865(a)(1) of the Act provides that, if the Secretary of the Department of Health and Human Services (the Secretary) finds that accreditation of a provider entity by an approved national accreditation organization meets or exceeds all applicable Medicare conditions or requirements, we may “deem” the provider entity to be in compliance. Accreditation by an accrediting organization is voluntary and is not required for Medicare participation.

Part 488, subpart A implements the provisions of section 1865 of the Act. It requires that a national accrediting organization applying for approval of its Medicare accreditation program must provide CMS with reasonable assurance that the accrediting organization requires its accredited provider or supplier entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning the approval of accrediting organizations are set forth at §488.5. The regulations at §488.5(e)(2)(i) require an accrediting organization to reapply for continued approval of its Medicare accreditation program every 6 years or sooner as determined by CMS. The American Association for Accreditation of Ambulatory Surgery

Facilities (AAAASF's) current term of approval for their RHC accreditation program expires March 23, 2016.

II. Application Approval Process

Section 1865(a)(3)(A) of the Act requires that we publish, within 60 days of receipt of an organization's complete application, a notice identifying the national accreditation body making the request, describing the nature of the request, and providing at least a 30-day public comment period. We have 210 days after the date of receipt of a complete application to publish a notice announcing our approval or denial of an application.

III. Provisions of the Proposed Notice

On September 25, 2015, we published a proposed notice in the **Federal Register** (80 FR 57822) entitled, "Application from the American Association for Accreditation of Ambulatory Surgery Facilities for Continued Approval of its Rural Health Accreditation Program." In that notice, we detailed our evaluation criteria. Under section 1865(a)(2) of the Act and in our regulations at §488.5, we conducted a review of AAAASF's Medicare RHC accreditation application in accordance with the criteria specified by our regulations, which include, but are not limited to the following:

- An onsite administrative review of AAAASF's: (1) Corporate policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training, monitoring, and evaluating its RHC surveyors; (4) ability to investigate and respond appropriately to complaints against accredited RHCs; and, (5) survey review and decision-making process for accreditation.
- The comparison of AAAASF's Medicare accreditation program standards to our current Medicare RHC conditions for certification.

- A documentation review of AAAASF's survey process to:

++ Determine the composition of the survey team, surveyor qualifications, and AAAASF's ability to provide continuous surveyor training.

++ Compare AAAASF's processes to those we require of State survey agencies, including periodic resurvey and the ability to investigate and respond appropriately to complaints against accredited RHCs.

++ Evaluate AAAASF's procedures for monitoring RHCs it has found to be out of compliance with AAAASF's program requirements. (This pertains only to monitoring procedures when AAAASF identifies non-compliance. If noncompliance is identified by a State survey agency through a validation survey, the State survey agency monitors corrections as specified at §488.9(c)(1).)

++ Assess AAAASF's ability to report deficiencies to the surveyed RHC and respond to the RHC's plan of correction in a timely manner.

++ Establish AAAASF's ability to provide CMS with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

++ Determine the adequacy of AAAASF's staff and other resources.

++ Confirm AAAASF's ability to provide adequate funding for performing required surveys.

++ Confirm AAAASF's policies with respect to surveys being unannounced.

++ Obtain AAAASF's agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey as we may require, including corrective action plans.

In accordance with section 1865(a)(3)(A) of the Act, the September 25, 2015 proposed

notice also solicited public comments regarding whether AAAASF's requirements met or exceeded the Medicare conditions for certification for RHCs. We received no public comments in response to our proposed notice.

IV. Provisions of the Final Notice

A. Differences Between AAAASF's Standards and Requirements for Accreditation and Medicare Conditions and Survey Requirements

We compared AAAASF's RHC accreditation requirements and survey process with the Medicare conditions for certification at part 491, subpart A and the survey and certification process requirements at parts 488 and 489. We reviewed AAAASF's RHC accreditation program application as described in section III of this final notice. In response to our request AAAASF revised its standards and certification processes to ensure that its surveyors complete the required number of medical record reviews for each accredited facility.

B. Term of Approval

Based on our review and observations described in section III of this final notice, we approve AAAASF as a national accreditation organization for RHCs that request participation in the Medicare program, effective March 23, 2016 through March 23, 2022.

V. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

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Dated: February 9, 2016.

Andrew M. Slavitt,

Acting Administrator,

Centers for Medicare & Medicaid Services.

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